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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/065,200	09/25/2002	Nancy Wisnewski	FC-4-1	8153

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/065,200

Applicant(s)

WISNEWSKI ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9,10,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3, 5-7, 10, 12 is/are rejected.
- 7) ☒ Claim(s) 4,9 and 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group I in Paper No. 6 is acknowledged. Claims 1, 3-7, 9, 10, 12, and 13 are pending and under examination.

### *Specification*

2. The disclosure is objected to because of the following informalities: Application 09/435019 has now issued as U.S. patent 6489140. The first line of the specification should be updated accordingly.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5-7, and 10 are rejected under 35 U.S.C. 102(a) as being anticipated by WO9835550 (Heath et al., 1998).

WO9835550 teaches a sequence that encodes a protein comprising a sequence of >95% homology to instant SEQ ID NO 64, thus anticipating the limitations of claim 1. See example 2, figure 4, and sequence alignment attached to back of document. Expression by hosts cells and transcriptional control are taught on p. 4, lines 17-35 and p. 5, lines 1-5, anticipating the

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limitations of claims 5-7. The addition of an excipient, as claimed in claim 10, does not change the nature of the claimed nucleic acid or confer patentable distinctness. The addition of an excipient is further inherent in the process of transfecting a host cell. Thus the limitations of claim 10 are also anticipated.

5. Claims 1, 5-7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO9637609 (Greenland et al., 1996) and Kothapelli et al. (Dev. Gen. 17 (4), pp. 319-330, 1995).

WO9637609 teaches three sequences that encode a protein comprising a sequence of >95% homology to instant SEQ ID NO 64, thus anticipating the limitations of claim 1. See claims 1-3, pp. 41-45, and attached sequence alignments. Expression is taught on p. 8, lines 3-16, anticipating the limitations of claims 5-7 and 10.

Kothapelli et al. teaches cloning and expression of an ecdysone receptor comprising a sequence having >96% homology to instant SEQ ID NO: 64; see abstract and sequence alignment provided (GenBank accession no. U29531, 1999).

6. Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujiwara et al. (Insect Biochem. Mol. Biol. 25 (7), pp. 845-856, 1995) and Kamimura et al. (Comp. Biochem. Physiol. 113B, pp. 341-347, 1996).

Fujiwara et al. and Kamimura et al. each teach cloning of an ecdysone receptor comprising a sequence that has >96% homology to instant SEQ ID NO: 64, thus anticipating claim 1. See abstract and sequence alignments provided (GenBank accession nos. U19812, 1996, and D43943, 1999). Sequencing of these polynucleotides required the presence of an excipient, thus anticipating the limitations of claim 10.

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7. Claims 1, 5-7, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patents 6300488 (Gage et al., filed 1997) and 6379945 (Jepson et al., filed 1996).

The '488 patent teaches SEQ ID NO: 2, which encodes a sequence comprising a sequence of >96% homology to instant SEQ ID NO: 64, thus anticipating instant claim 1. See attached sequence alignment. Expression is taught in, for example, column 15, lines 44-66, and column 16, lines 1-2, anticipating the limitations of claims 5-7 and 10.

The '945 patent teaches SEQ ID NOs: 2, 9, and 10, which encode sequences comprising sequences of >95% homology to instant SEQ ID NO: 64, thus anticipating instant claim 1. See attached sequence alignment. Expression is taught in, for example, column 7, lines 1-10, anticipating the limitations of claims 5-7 and 10.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujiwara et al. and Kamimura et al.

Each of these references teaches a polynucleotide encoding a polypeptide of >96% homology to instant SEQ ID NO: 64. These references fail to teach expression vectors, host cells, and means of expression. However, it would have been *prima facie* obvious to one of ordinary skill in the art to express the protein using such approaches. One of ordinary skill would have been motivated to do so because each of these references teaches that these proteins are of interest in insect development and reproduction, and thus one of ordinary skill would have readily appreciated that the expressed protein would be a useful tool for further study.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 3 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to polynucleotides that encode ecdysone receptors. However, they encompass the polynucleotides of SEQ ID NOs: 7 and 10, which are antisense to SEQ ID Nos 5 and 6 respectively and thus do not encode ecdysone receptors.

***Allowable Subject Matter***

12. Claims 4, 9, and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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CLAIMS 1, 3, 5-7, 10, AND 12 ARE REJECTED. CLAIMS 4, 9, AND 13 ARE OBJECTED TO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

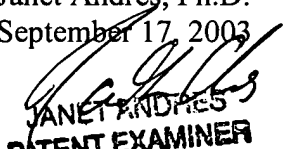
Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.

September 17, 2003

  
JANET ANDRES  
PATENT EXAMINER